

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	T	See Notification of Transmittal of International			
PU3375/PCT	FOR FURTHER ACTION Preliminary Examination Report (Form PCT/IPEA/416)				
	i les de la companya	//vear) Priority date (day/month/year)			
International application No.	International filing date (day/month	07/10/1997			
PCT/EP98/06278	05/10/1998	0771071337			
International Patent Classification (IPC) or na A61K31/00	itional classification and IPC				
A61K31/00					
Applicant					
GLAXO GROUP LIMITED et al.					
This international proliminant even	sination report has been prepared	by this International Preliminary Examining Authority			
This international preliminary exam and is transmitted to the applicant a	according to Article 36.	g by this internationally remaining extension,			
	-				
2. This REPORT consists of a total of	f 5 sheets including this covers	heet.			
☐ This report is also accompanie	ed by ANNEXES, i.e. sheets of the	ne description, claims and/or drawings which have			
been amended and are the ba	sis for this report and/or sheets on the struction of the Administrative Instruction.	containing rectifications made before this Authority ons under the PCT).			
(See Fulle 70.10 and Section of	of the Administrative men gen	,			
These annexes consist of a total of	f sheets.				
i ·					
3. This report contains indications rel	ating to the following items:				
l ⊠ Basis of the report					
Ⅱ □ Priority					
III 🛛 Non-establishment of	opinion with regard to novelty, in	ventive step and industrial applicability			
IV 🛭 Lack of unity of invent					
V ⊠ Reasoned statement of citations and explanat	under Article 35(2) with regard to tions suporting such statement	novelty, inventive step or industrial applicability;			
VI Certain documents ci	ted				
VII Certain defects in the	international application				
VIII Certain observations of	on the international application	•			
		·			
Date of submission of the demand Date of completion of this report					
05/05/1999		2 3. 02 . 😃			
Name and mailing address of the internation		ized officer			

Cattell, James

Telephone No. +49 89 2399 8468

European Patent Office

Fax: +49 89 2399 - 4465

Tel. +49 89 2399 - 0 Tx: 523656 epmu d

D-80298 Munich

International application No. PCT/EP98/06278

1	Ras	ic	of	the	report
	Das	13	U	"	1 choir

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.): Description, pages: as originally filed 1-15 Claims, No.: as originally filed 1-10 2. The amendments have resulted in the cancellation of: ☐ the description. pages: ☐ the claims, Nos.: ☐ the drawings, sheets: 3.

This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)): 4. Additional observations, if necessary: III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of: ☐ the entire international application. claims Nos. 4, 8 (1, 5, 9 partially), 5-7(IA). because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does

not require an international preliminary examination (specify):

International application No. PCT/EP98/06278

		•
		the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
		the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
	Ø	no international search report has been established for the said claims Nos. 1, 4, 5, 8, 9.
IV.	. Lac	k of unity of invention
1.	In r	esponse to the invitation to restrict or pay additional fees the applicant has:
		restricted the claims.
		paid additional fees.
		paid additional fees under protest.
		neither restricted nor paid additional fees.
2.	Ø	This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3.	This	s Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
		complied with.
	⊠	not complied with for the following reasons:
		see separate sheet
4.		nsequently, the following parts of the international application were the subject of international preliminary mination in establishing this report:
		all parts.
	\boxtimes	the parts relating to claims Nos. 2, 3, 6-7, 10 (1, 5, 9 partially).

International application No. PCT/EP98/06278

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes:

Claims 1, 2, 3,5, 6, 7

No:

Claims 9,19

Inventive step (IS)

Yes: No:

Claims

Claims 1, 2, 3, 5,6, 7

Industrial applicability (IA)

Yes:

Claims 1, 2, 3, 9, 10 No: Claims

2. Citations and explanations

see separate sheet

EXAMINATION REPORT - SEPARATE SHEET

Ш.

- 1. An international examination report can only be drawn up on searched subjectmatter (Rule 66.1(e) PCT).
- 2. Claims 5, 6 and 7 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

IV.

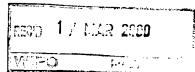
3 The IPEA agree with the assessment of unity made by the ISA under Rule 13.1 PCT. Once it is known and obvious that and 5-HT₃ receptor antagonists can be used to treat IBS (see section V below) the use of the individual agents exemplified in claim 8 are regarded as being different "inventions".

٧.

- 4. Document D1 (EP-A-0,306,323) discloses on page 4 lines 1 and 26 the use of alosetron to treat IBS.
 - Document D2 (Foster et al 1997) and D3 (Barman et al 1996) disclose the use of alosetron to treat IBS.
 - These disclosures fall within the scope of product claims 9 and 10 under Article 33(2) PCT.
- 5. Once the use of alosetron in IBS patients is known (from an one of D1 to D3) the optimisation of the treatment would be obvious. The discovery of treating female nonconstipated IBS patients would occur inevitable from these obvious trials. Claims 1, 2, 3, 5, 6 and 7 therefore do not meet the requirements of Article 33(3) PCT.







(PCT Article 36 and Rule 70)

Applicant's o	_	int's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)				
International application No.			International filing date (day/month	n/year)	Priority date (day/month/year)			
PCT/EP9	8/06:	278	05/10/1998		07/10/1997			
A61K31/0		nt Classification (IPC) or na	tional classification and IPC					
Applicant GLAXO G	RO	UP LIMITED et al.						
	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.							
2. This R	EPC	RT consists of a total of	5 sheets, including this cover s	heet.				
be	en a	mended and are the bas	d by ANNEXES, i.e. sheets of the sis for this report and/or sheets of the Administrative Instruction	ontaining re	n, claims and/or drawings which have octifications made before this Authority ne PCT).			
These	ann	exes consist of a total of	sheets.					
3. This re	eport	contains indications rela	ating to the following items:					
1	×	Basis of the report						
Ш								
111	\boxtimes	Non-establishment of o	ppinion with regard to novelty, in	ventive step	and industrial applicability			
IV .	\boxtimes	Lack of unity of invention	on					
V	×		nder Article 35(2) with regard to ons suporting such statement	novelty, inve	entive step or industrial applicability;			
VI		Certain documents cite	ed					
VII		Certain defects in the in	nternational application					
VIII		Certain observations o	n the international application					
					1			
Date of sub	missi	on of the demand	Date of	completion of	this report			
05/05/1999					2 8. 02. 00			
Name and mailing address of the international				zed officer	SPI SCHES AN	ieve		
preliminary		ining authority: opean Patent Office			(g. S. S.	- * <u>*</u>		
911	D-8	0298 Munich		l, James				
<u> </u>		+49 89 2399 - 0 Tx: 52365 : +49 89 2399 - 4465	· ·	one No. +49 8	9 2399 8468	Disc As		



International application No. PCT/EP98/06278

1	l. I	Ra	eie	of	the	re	no	d
1		u	313	v	1110		~~	

1.	resp	This report has been drawn on the basis of (substitute sheets which have been lumished to the receiving Office response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):					
	Des	cription, pages:					
	1-15	5	as originally filed				
	Clai	ims, No.:					
	1-10)	as originally filed				
2.	The	amendments have	e resulted in the cancellation of:				
		the description,	pages:				
		the claims,	Nos.:				
		the drawings,	sheets:				
3.		This report has be considered to go	een established as if (some of) the amendments had not been made, since they have been beyond the disclosure as filed (Rule 70.2(c)):				
4.	Add	ditional observation	ns, if necessary:				
H	. Noi	n-establishment o	of opinion with regard to novelty, inventive step and industrial applicability				
Th or	ne qu to b	estions whether the industrially applic	ne claimed invention appears to be novel, to involve an inventive step (to be non-obvious), cable have not been examined in respect of:				
		the entire internat	tional application.				
	×	claims Nos. 4, 8 ((1, 5, 9 partially), 5-7(IA) .				
be	cau	se:					
		the said internation	onal application, or the said claims Nos. relate to the following subject matter which does emational preliminary examination (<i>specify</i>):				

International application No. PCT/EP98/06278

		the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
		the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
	Ø	no international search report has been established for the said claims Nos. 1, 4, 5, 8, 9
IV.	Lac	k of unity of invention
1.	In re	esponse to the invitation to restrict or pay additional fees the applicant has:
		restricted the claims.
		paid additional fees.
		paid additional fees under protest.
		neither restricted nor paid additional fees.
2.	×	This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3.	Thi	s Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
		complied with.
	×	not complied with for the following reasons:
		see separate sheet
4.		nsequently, the following parts of the international application were the subject of international preliminary Imination in establishing this report:
		all parts.
	\boxtimes	the parts relating to claims Nos. 2, 3, 6-7, 10 (1, 5, 9 partially).





International application No. PCT/EP98/06278

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes:

Claims 1, 2, 3,5, 6, 7

No:

Claims 9,19

Inventive step (IS)

Yes: No:

Claims

Claims 1, 2, 3, 5,6, 7

Industrial applicability (IA)

Yes:

Claims 1, 2, 3, 9, 10

No: Claims

2. Citations and explanations

see separate sheet

INTERNATIONAL PRELIMINARY International application No. PCT/EP98/06278 EXAMINATION REPORT - SEPARATE SHEET

III.

- 1. An international examination report can only be drawn up on searched subjectmatter (Rule 66.1(e) PCT).
- 2. Claims 5, 6 and 7 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

IV.

The IPEA agree with the assessment of unity made by the ISA under Rule 13.1 PCT. Once it is known and obvious that and 5-HT₃ receptor antagonists can be used to treat IBS (see section V below) the use of the individual agents exemplified in claim 8 are regarded as being different "inventions".

V.

- 4. Document D1 (EP-A-0,306,323) discloses on page 4 lines 1 and 26 the use of alosetron to treat IBS.
 - Document D2 (Foster et al 1997) and D3 (Barman et al 1996) disclose the use of alosetron to treat IBS.
 - These disclosures fall within the scope of product claims 9 and 10 under Article 33(2) PCT.
- 5. Once the use of alosetron in IBS patients is known (from an one of D1 to D3) the optimisation of the treatment would be obvious. The discovery of treating female nonconstipated IBS patients would occur inevitable from these obvious trials. Claims 1, 2, 3, 5, 6 and 7 therefore do not meet the requirements of Article 33(3) PCT.